IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S DEPOSITION DESIGNATIONS OF JANICE CONNOR TAKEN APRIL 21, 2015

BSC Designations	Objection	Plaintiffs Counter Designation
jc042115, (Pages 436:25 to 439:18) 436 25 Q. Okay. I now want to talk about 437 1 Boston Scientific's devices that it has marketed 2 for the treatment of pelvic organ prolapse, the 3 Pinnacle and Uphold devices. 4 Did Boston Scientific conduct 5 clinical trials in women specifically with those 6 two devices prior to going to market? 7 A. No. 8 Q. Why not? 9 A. No. For, actually, both of those 10 devices, they're made from Polyform. So, it's, 11 again, a type one macroporous monofilament 12 polypropylene mesh used to treat pelvic organ 13 prolapse. 14 That product was already on the 15 market prior to Pinnacle and Uphold being placed 16 on the market. So, again, we had not -- Pinnacle		*[Counter to 436:25-438:5]* *jc042115, (Page 385:18 to 385:23)* *385* *18 Q. (By Ms. Fitzpatrick) And, Ms.* *19 Connor, can you identify the document that I've* *20 handed you, Exhibit 1323?* *21 A. This is a reviewer summary report of* *22 the research grant Dr. Moalli submitted. I'm* *23 looking for a date on here.* jc042115, (Pages 386:25 to 388:11) *386* *25 Q. And, she has now submitted in 2011 a*

and Uphold weren't new products. They were basically a package of a product put in a different shape and placed on the market of a product that was already on the market. Two products, the Capio, the delivery system, and the mesh. So, again, we didn't create a new product. We basically put them together in a different package and then marketed it that way. 438 So, we didn't -- I'm sorry. I think your question was why didn't we run studies. We had the Polyform mesh and we were able to use data from that mesh, human data, to understand how that mesh was working. *** Q. And, generally, what do the overall body of studies show with regard to the Pinnacle 439 and Uphold devices? A. Overall it shows that the products are safe and that they're effective. So, overall, the safety, again, looking at the complications. So, how do the patients feel, what events have they experienced, have they had any pain or any other complications occurred. Those events that have occurred in women are similar to events that occur for surgery for POP without a device and also similar to other devices. So, we show that overall the product is safe. And, again, overall the product's working. So, the symptoms that the patients experienced, bulging, issues with urine frequency, issues with bowel, issues or dysfunction with sexual functioning, those have been improved.	438:24-439:18 FRE 401, 402; 403 701, 702	*387* *research grant proposal to you concerning polyform synthetic mesh, correct?* *A. That is correct.* *Q. And, polyform synthetic mesh is the mesh that is used in both the Pinnacle and the Uphold devices for Pelvic Organ Prolapse, correct?* *A. That is correct.* *Q. Okay. And, Dr. Moalli has asked for funding from Boston Scientific to do an animal model-based research, correct?* *A. That is correct.* *Q. And, what she is looking at is that she's hypothesizing that meshes, she says it here, "with increased stiffness will have increased tensile strength following tissue incorporation at the expense of tissue function. Accelerated tissue contraction, increased vaginal wall stiffness, decreased distension and elasticity, decreased compliance, and poor contractility, resulting in poor re-approximation of the prolapsed vagina to the supported condition."* *Is that correct?* *A. Yes.* *388* *Q. So, her hypothesis here is that the stiffer the mesh the worse the outcome for patients for these issues; such as, vaginal wall*

		4 stiffness, elasticity, compliance and the like, *5 correct?* *6 A. In so many words, yes.* *7 Q. Okay. So, she has submitted this to* *8 Boston Scientific and asked Boston Scientific* *9 specifically for funding to look at these issues* *10 in the polyform mesh. Correct?* *11 A. Correct.* *jc042115, (Pages 392:14 to 393:16)* *392* *14 You were a reviewer on* *15 this ISR, correct?* *16 A. That is correct.* *17 Q. And, from -- and you recommended* *18 that the ISR not be funded, correct?* *19 A. I believe so. Let me see where I* *20 indicated. Okay. Yes, I see it.* *21 Q. Okay. And, we have a gentleman from* *22 safety who reviewed it who gave conditional* *23 approval, correct?* *24 A. That's actually a woman. And,* *25 yes.* *393* *1 Q. Oh, excuse me.* *2 A. It's all right.* *3 Q. And, Robert Walsh from medical* *4 sciences. And, looks like at the time of, at* *5 least the generated copy we have, he had not* *6 reviewed it and made a recommendation, correct?* *7 A. Yes, I see that. There is no --*

		8 it's not checked off on this form. *9 Q. Okay. And, ultimately Boston* *10 Scientific did not fund Dr. Moalli's request,* *11 correct?* *12 A. That's correct.* *13 Q. Okay. And, you reviewed this on* *14 March 21st, 2011, and made the recommendation* *15 that you not fund it?* *16 A. Correct.* *jc042115, (Page 396:10 to 396:13)* *396* *10 You have here under negative, you* *11 have, concern over negative results. Those are* *12 your words, correct?* *13 A. That is correct.* *jc042115, (Page 401:4 to 401:21)* *401* *4 You just told me as a result of this* *5 proposal for Dr. Moalli that you thought that the* *6 human data on how the Polyform interacts with a* *7 woman's pelvis is the most important information* *8 that is available to answer these questions,* *9 correct?* *10 A. In so many words I think, yes.* *11 Q. Okay. Yet, Boston Scientific didn't* *12 do any human or clinical studies on the effect of* *13 Polyform in a woman's pelvis before it marketed* *14 and sold it as a permanent medical implant,* *15 correct?*

		16 MR. ANIELAK: Form. *17 THE WITNESS: Boston Scientific did* *18 not for several reasons.* *19 Q. (By Ms. Fitzpatrick) Did Boston* *20 Scientific do it or not, Ms. Connor?* *21 A. We did not.*
jc042115, (Pages 442:4 to 447:23) *** 14 Q. So, would the clinical department 15 then provide the input for the Advantage and the 16 Obtryx about the clinical literature and the 17 studies that have been done on similar products 18 prior to those products going to market? 19 A. Correct. ***	444:14-19 FRE 403 Misleading and Confusing	
jc042115, (Pages 450:3 to 451:11) 450 3 Q. And, has Boston Scientific funded 4 and supported clinical trials of the Uphold 5 device? 6 A. Yes. 7 Q. And, generally, explain how that 8 happens. How does Boston Scientific fund and 9 support research into medical devices? 10 A. There is two different ways. One 11 way is if Boston Scientific sponsors that 12 research project. And that means that Boston 13 Scientific, along with a physician, has that 14 scientific question, develops that study 15 protocol, develops what assessments that will be 16 undertaken by the patient to answer those 17 questions. 18 The sponsored study is when Boston 19 Scientific has the responsibility over the study, 20 over the conduct of the study. We don't treat 21 patients. The physicians treat patients. We 22 don't see the patients in the office. The 23 physicians see the patients. We're just 24 responsible for ensuring the physicians are 25 conducting the study and we understand the 451 1 information. 2 The other way that we get involved 3 in clinical studies is by the research grants. 4 And they're also -- another name for that is	450:3-451:11 FRE 401; 402; 403 Funding and supporting clinical trials post-implantation of Plaintiffs is irrelevant to BSC's conduct in 2010 and will mislead the jury.	

investigator sponsored research studies or ISRs. Same term. This is when physicians will request support from Boston Scientific, either through funding, dollars, or product and basically are looking for that assistance in conducting that research study.		
jc042115, (Pages 451:13 to 452:10) 451 When looking at what Boston Scientific studies, the company has either funded or supported, it would include both the sponsored research and the ISR studies; is that right? A. That's correct. Q. And, then, tell the jury what an independent study is. What does that mean? A. An independent study is a study that doesn't meet any of the other two criteria, basically. It is a study that physicians run on their own in their practice and they don't require or request any support from Boston Scientific. 452 Q. What are the main differences between the Boston Scientific sponsored or the investigator sponsored? A. You know, there are more similarities than differences. So, these are still studies where physicians are treating the patients. They're collecting the data. They're asking the questions. They're giving their input on the data.	451:13-452:10 FRE 401; 403 Funding and supporting clinical trials post-implantation of Plaintiffs is irrelevant to BSC's conduct in 2010 and will mislead the jury.	
jc042115, (Pages 452:13 to 453:10) 452 The difference is on who has overall the responsibility over the conduct of a study. And that basically means if there was a time where the study results had to be reported to an agency or another company, who has that responsibility to write that report. That's the main difference. For a sponsored study, it's Boston Scientific who has that responsibility. For an investigator sponsored research study, it's the investigator who has that responsibility. Q. When looking at the literature on Boston Scientific studies, would it be	452:13-453:10 FRE 401; 402, 403 Funding and supporting clinical trials post-implantation of Plaintiffs is irrelevant to BSC's conduct in	

453 1 appropriate to just dismiss out of hand any of 2 these kinds of studies? 3 A. No. So, again, when I said -- so, 4 there is more similarities than differences. 5 These are still patients being treated in a 6 hospital setting by a physician. And, the data 7 are still collected the same way and reported. 8 If you only looked at one, you'd be missing out 9 on important data from the other studies and vice 10 versa.	2010 and will mislead the jury.	
jc042115, (Pages 454:20 to 456:12) 454 20 Q. Okay. And, I know you went into it 21 a little bit, but I want to talk about the ISR 22 program and the R&E committee, the committee that 23 examines some of these ISR requests. 24 Explain to the jury what the R&E 25 committee is and how it does its job. 455 1 A. The R&E committee is a -- it stands 2 for the research and education committee. Is a 3 committee made up of different departments in the 4 division. For example, the research and 5 development department, the regulatory 6 department, medical, clinical. 7 And these different departments give 8 feedback on research grants when they're 9 submitted. So, these -- there is, for example, 10 from a medical standpoint, the medical director, 11 who is the medical representative on this 12 committee, reviews a research proposal from a 13 physician and comments on the study design, will 14 it answer the questions that are asked. Is there 15 enough -- are there enough patients proposed to 16 be followed in this study that will give that 17 answer. Has this physician conducted research 18 before, are they qualified to conduct research. 19 Is there a safety plan in place. 20 So, each different person 21 representing their department is part of this 22 committee and looks overall at the proposal from 23 the physicians. 24 Q. Is the research and grant committee, 25 is that similar to other organizations that 456 1 have -- that fund clinical research?	454:20-456:12 FRE 401, 402, 403 Funding and supporting clinical trials post-implantation of Plaintiffs is irrelevant to BSC's conduct in 2010 and will mislead the jury.	

A. It is. So, many corporations outside of the company have a similar program. So, there are -- definitely, it's just part of connecting research for companies who will have research that they directly manage, which is the sponsored piece of the puzzle, and there is also research that they fund. And, there is actually many different larger, Stanford, for example, Mayo Clinic, big hospitals that have direct input into research committees for future proposals.		
jc042115, (Pages 458:25 to 460:11) *** Q. And, then, in terms of how physicians are then made aware of the results of clinical research, how does that happen? Explain that process. A. They're published, basically. So, overall, when these studies are run, whether they're sponsored or funded, the physician has an 460 obligation in the company to make the results public. So, there is different ways these results can be presented at a medical society. And whether it's in a format where the physician stands at a podium and talks about the data or it's in a format where the data are printed on a large poster and placed in an exhibit hall with other posters of scientific studies. Or the study results are published in a manuscript. So, it's in a medical journal where that study is printed, basically.	459:19-460:11 FRE 401; 403. The existence of post-implantation publications is irrelevant to BSC's conduct in 2010 and will mislead the jury.	
jc042115, (Pages 460:24 to 461:9) 460 Q. With regard to the Uphold device. Has Boston Scientific funded and supported 461 clinical studies of the Uphold device? A. Yes. Q. And, have those studies been completed? A. Yes. Q. And, have those studies of the Uphold device been presented and published to physicians? A. Yes.	460:24-461:9 The existence of post-implantation publications is irrelevant to BSC's conduct in 2010 and will mislead the jury.	
jc042115, (Pages 462:9 to 465:1) **462**	462:9-465:1	

Exhibit 1328, BSC Pelvic Floor Clinical Cadence, marked) Q. (By Mr. Anielak) All right. I've marked as Exhibit 1328 a Boston Scientific document entitled BSC Pelvic Floor Clinical Cadence. Explain to the jury what this is. A. This is a snapshot in time of the clinical studies that were -- either there is some future trials planned, funded, sponsored from 2009 through 2012 for the pelvic floor devices. Q. So, the snapshot in time for this particular summary is in 2009; is that right? A. That's correct. Q. And, describe for the jury, just orient the jury to what the shading represents 463 and what information is presented on here because there is a lot going on. A. Yeah, it's a busy slide. So, there -- basically the trials, all the different studies are listed on that left column. And, if you follow those across to the right, there is long arrow with different colors on it. And, the different colors mean the different phases of a clinical study. And, I believe I have a little key on the bottom there. And it shows that the different shading or colors line up to different phases. So, for example, studies typically start with the enrollment phase, which mean the patients are asked to be in the clinical study. Each clinical study has a certain number of patients that they need from a statistical point of view, and that they're looking to recruit in the study. So, that's the first phase. When that phase is complete, there is typically a phase where you follow patients. So, this is when patients are followed forward in time to collect data. So, I talked about some of 464 the data that's collected. Each study has a certain time as to how long they would like these patients to be seen, as to how long after the treatment they will collect data. After that phase, typically the data	FRE 401, 402, 403 Post Implantation Conduct	

are analyzed and a report is generated, which is the shading with some lines there. And, then, finally the data are published in some format. Q. So, in 2009, describe for the jury what studies Boston Scientific was supporting with regard to the Uphold device? A. So, if I go through the list. Little difficult with the shading and it's black and white. But there is an Uphold study by Dr. Sands. There is another Uphold, it's an economic study. And it's Dr. Culligan. Q. On the Dr. Sands Uphold study. Has that study been completed? A. Yes. Q. And, has that study been published and presented to physicians, the results of that study? 465 A. Yes, it has.		
jc042115, (Pages 469:10 to 471:2) *** (Exhibit 1329, Women's Health Clinical Program Cadence, marked) Q. (By Mr. Anielak) I've marked as Exhibit 1329 what appears to be a similar document to the other cadence document we just looked at. But explain to the jury what this is. 470 A. It is similar. It is, again, a snapshot in time. I believe this is March, 2012, of the clinical program for the women's health products. Q. So, again, orient to the jury to how the chart is set up and what it means. A. Mm-hmm. There is different rows, basically. So, there is -- the top part here is on slings. So, it has, again, the column right to the right of the word slings, three different clinical studies that were on-going at the time of this snapshot. So, there are three different studies there. And, again, if you follow it to the right, the different colors and shading will show the different phases that I had referred to before on about -- in a clinical trial. Enrollment, follow-up, and then the finalization,	469:18-471:2 FRE 401; 403 Post implant clinical studies have no relevance to BSC's conduct in 2010.	

the analysis, and the final report. These little stars, basically indicate at what point the data will be available to the public. And, it's a projected date. The studies, obviously, can be slower or faster depending on the study, the design, many different variables. So, that's kind of an 471 estimated time point of when the data will be available to the public.		
jc042115, (Pages 472:6 to 473:19) 472 Q. There is a number of studies that were on-going in 2012 with regard to Uphold, right? A. Yes. Q. And, there is one that says Uphold retro pain. Describe for the jury what that particular study is. A. It was a comparative study in patients who were treated with the Uphold device, and then patients who were treated with native tissue. So, meaning that for pelvic organ prolapse, the physician basically used sutures, stitches with the patient's own tissue to fix that pelvic organ prolapse. So, it was a short-term study assessing the postop pain experienced from patients. Q. And, have the results of that study been presented? 473 A. Yes. Q. So, that study has been completed? A. Yes. Q. And, there is other Uphold studies identified on here. The uphold Nordic study, what study is that? A. That is a clinical study by Dr. Daniel Altman in the Nordic countries. He had done a clinical study assessing data on patients treated with Uphold Lite, and they were treated out to one year. There were over 200 patients in that clinical study. Q. And, has that study been completed on Uphold? A. It has. Q. And, have the results of that study	472:6-473:19 FRE 401; 402403 Post implant clinical studies have no relevance to BSC's conduct in 2010.	

18 been presented? 19 A. Yes.		
jc042115, (Pages 473:22 to 474:5) 473 22 Does Boston Scientific continue to 23 fund and support research into its mesh 24 devices? 25 A. We do, yes. 474 1 Q. And, so we could look at continued 2 cadence documents up until today that would have 3 clinical studies on them that show Boston 4 Scientific funding studies on its mesh devices? 5 A. Yes, that's correct.	473:22-474:5 FRE 401; 403 Post implant clinical studies have no relevance to BSC's conduct in 2010.	
jc042115, (Pages 479:9 to 481:5) 479 9 Is a randomized controlled trial the 10 only study design that can provide scientific 11 information about how a device performs in 12 women? 13 A. No, not all all. There are many 14 different types. So, I mentioned a few of those. 15 So, there is comparing products to each other by 16 not randomizing. There is doing studies where 17 it's just one treatment that's offered. So, it's 18 definitely not the only way to give an answer to 19 a question. 20 Q. And, are there strengths and 21 limitations to all study designs? 22 A. There are. In a randomized study, 23 for example, the strengths are that you try to 24 narrow down the variables that you study, so you 25 feel as if you get -- you get the answer. There 480 1 is only one reason why you get that answer, 2 because of that medical intervention. 3 But there is limitations. For 4 example, in a surgical trial you can't 5 necessarily limit all those variables because 6 patients anatomy is different. There is not a 7 way to absolutely know that the tissue quality in 8 one patient is the same as the tissue quality in 9 another. There is not a way to randomize that. 10 There is not a way to randomize physicians 11 surgical skills within the setting of that 12 surgery. There is things that obviously happen 13 in a surgery that the physician has to react to.		*[Counter Designation to 479:9-481:5]* *jc031115, (Pages 255:2 to 256:12)* *255* *2 Q. And how many articles are in the* *3 medical -- full-length peer-reviewed articles* *4 are in the medical literature concerning the* *5 Uphold?* *6 (Witness reviewing document.)* *7 A. There are four.* *8 BY MS. FITZPATRICK:* *9 Q. How many of those are BSC-funded?* *10 A. One.* *11 Q. Could you tell me what those four are?* *12 A. The first one is Dr. Larouche,* *13 "Outcomes of Trocar Guided Gynemesh Versus* *14 Single Incision Trocar-Less Polyform* *15 Transvaginal Mesh Procedure. This actually does* *16 include Pinnacle as well, so my earlier number* *17 on published Pinnacle, I just want to --* *18 Q. Went from zero to one?*

That's not a controlled environment where you can make sure that doesn't happen. So, that's a limitation to a randomized trial where you can't rule those out. So, when you get the results, can you absolutely guarantied say that that's because of the intervention not because of maybe some of these other variables that you can't control. Q. But with all study designs, there are textbooks and classes that last all year long in college that talk about the strengths and limitations of different study designs, right? 481 A. True. Yes. Q. Not withstanding that, has Boston Scientific conducted randomized controlled trials on its mesh devices? A. Yes.	481:2-5 FRE 403 Misleading and Confusing as it lumps all "mesh" devices together	*A. -- double-check that's in there.* *Two. One to two.* *Q. One to two. Okay.* *A. So I read that one, too.* *Jirschele, J-I-R-S-C-H-E-L-E,* *published 2014, "Multicenter Prospective Trial to Evaluate Mesh Augmented Sacrospinous* *256* *Hysteropexy for Uterovaginal Prolapse."* *Dr. Rivaux, R-I-V-A-U-X, entitled "Uterovaginal Suspension Using a Bilateral Vaginal Anterior Sacrospinous Fixation with Mesh, Preliminary Results," this is in 2012.* *And then Dr. Vu, published 2012, "Minimal Mesh Repair for Apical and Anterior Prolapse, Initial Anatomical and Subjective Outcomes."* *Q. How many of those are randomized controlled trials?* *A. None of them.* *jc031115, (Page 257:1 to 257:4)* *257* *Q. You're not aware of any long-term randomized controlled trials for the Uphold that have safety as a primary endpoint, correct?* *A. Correct.*
jc042115, (Pages 495:2 to 500:2) 495 Q. (By Mr. Anielak) So, with regard to the POP devices, Uphold and Pinnacle were		*[Counter Designation to 499:13-500:2]*

launched in 2008 and 2009 time period, right?
A. That's correct.
Q. And, so, deciding whether or not a clinical trial was necessary prior to going to market, how did the -- how did Boston Scientific rely on the other devices that were already on the market?
A. So, we basically -- if you look at when the Pinnacle and Uphold were launched, there is or are many products that were already on the market.
So, specifically from Boston Scientific's standpoint, the Polyform mesh was on the market. And there were data available on the use of Polyform mesh for pelvic organ prolapse.
So, Boston Scientific looked at these devices, reviewed the clinical data that was available on all these devices prior to launching the Pinnacle and Uphold. So, all that information was available to us.
Q. So, was there information and data available regarding the use of these devices in

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women prior to Uphold and Pinnacle being sold?
A. Yes.
Q. And, was there data that Boston Scientific could review on Polyforms performance in women prior to going to market with Pinnacle and Uphold?
A. There was. So, Boston Scientific has a program internally where we monitor all of our devices. So, it's a safety surveillance program. So, we had information on the use of Polyform in Boston Scientific to understand then the use of that device in the Pinnacle and Uphold.
Q. So, explain that in a little bit more detail to the jury.
What is the data that Boston Scientific had to consider with regard to the performance of Polyform in terms of its performance in women?
A. So, safety data. So, we had data internally on any events that patients experienced or any device issues that physicians experienced. And that information is recorded

jc031115, (Page 94:21 to 94:23)

94

Q. The clinical data that you relied on was related to similar devices, correct?
A. Correct.

jc031115, (Page 96:3 to 96:18)

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Q. Are they made with the same resin?
A. So I don't know if they're made with the same resin. Yet we do have testing in those binders that is on our product compared to other products.
Q. Okay. And do you know whether they have the same antioxidant package?
MR. ANIELAK: Object to the form. Beyond the scope of the 30(b)(6) notice.
A. I don't know that.
BY MS. FITZPATRICK:
Q. Do you know whether they're the same, exact mesh woven the same way?
MR. ANIELAK: Beyond the scope of the 30(b)(6) notice.
A. I don't know that.

jc031115, (Pages 104:24 to 105:2)

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Q. But you don't actually know what those competitive devices, what polypropylene they

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were made of, correct?
A. I don't sitting here right now.

24 internally to Boston Scientific, which we had the 25 ability to review prior to the launch of Pinnacle 497 1 and Uphold. 2 Q. Is it common in the medical device 3 development for companies to rely upon similar 4 devices in terms of making decisions as to 5 whether a clinical trial is necessary prior to 6 going to market? 7 A. Yes, it is. 8 Q. So, explain that to the jury. Why 9 is that something that medical device companies 10 do? 11 A. When you're marketing a device, 12 whether it's, you know, brand new, never been 13 used before, or if it's similar to others, which 14 is an example for these devices. You will look 15 at existing literature to understand, is there 16 information already known that will assist in the 17 understanding of should a trial be done, what 18 information will it add, is there value in terms 19 of missing conclusions, is there anything more to 20 be learned. So, that is typically -- and how 21 companies and clinical research will proceed 22 forward. 23 Q. And, with regard to the Pinnacle and 24 Uphold device. 25 Explain for the jury what Polyform 498 1 is and what Capio is and how that relates to 2 Pinnacle and Uphold? 3 A. Polyform is a polypropylene mesh, 4 and it's a sheet mesh. So, it's not cut to a 5 certain small shape. It is a, basically a 6 square, rectangle, rectangle sheet of mesh. 7 And the physicians, when they 8 have -- when they use this product, they will cut 9 the mesh to a certain shape, and then use the 10 capio, which is a suturing device and place 11 sutures through that Polyform mesh, the other end 12 of the Capio and place it into the anatomy to 13 then fixate that into the body. That's what poly 14 -- well, that's how Polyform was used in many 15 different instances in 2005 forward. 16 Pinnacle device is basically taking 17 the polyform and the Capio, putting it in a 18 package together, but already doing the shaping 19 and the fixating to a delivery system in that 20 package, basically, if that makes sense.	497:2-22 FRE 401, 402, 403, 701, 702	

21 So, the Capio system is still part 22 of that because the Capio is used to place it in 23 the body, but the Pinnacle was basically taking 24 the Polyform, putting it into a shape, and 25 allowing for kind of a standardization for that 499 1 procedure. 2 Q. And, was the Uphold similar in terms 3 of using Polyform and cutting it into a shape? 4 A. Correct. So, it's just a different 5 and different fixating points that go in the 6 body. So, it is the similar situation where it's 7 Polyform into a shape with the Capio device. 8 Q. Okay. So, in terms of the mesh 9 that's used in Pinnacle and Uphold. 10 Was the mesh new, a new product on 11 the market in 2008? 12 A. No. 13 Q. And, was the use of polypropylene to 14 treat pelvic organ prolapse, was that something 15 that Boston Scientific came up with in 2008? 16 A. No. 17 Q. And, explain that to the jury. 18 A. No. So, if you look at the 19 timeline, these are polypropylene devices in 20 orange or in the other colors that are prior to 21 Pinnacle and Uphold, even Polyform. 22 Q. And, did Boston Scientific rely upon 23 the prior marketing of those devices in making a 24 determination that a clinical trial prior to 25 going to market wasn't necessary? 500 1 A. Right. So, we did review all that 2 information to make that decision.		
jc042115, (Page 501:6 to 501:10) 501 6 Q. (By Mr. Anielak) Ms. Connor, did 7 you help put together some slides that summarize 8 the clinical studies that had been conducted with 9 Boston Scientific devices? 10 A. I did.		
jc042115, (Pages 551:9 to 552:14) 551 9 (Exhibit 1339 marked for 10 identification) 11 Q. (By Mr. Anielak) And, I've marked 12 as deposition Exhibit 339. 13 Describe for the jury what this is. 14 A. It's a summary of the studies that 15 have been performed on Pinnacle and Polyform. 16 Q. So, why Pinnacle and Polyform	551:9-552:14 FRE 401; 402; 403; 1006	

together? A. So, Polyform is basically -- the Polyform mesh is a sheet mesh. Pinnacle is using that Polyform mesh in a certain shape. So, it's basically the Pinnacle device is the Polyform mesh with the Capio device. Q. And, how many women have been treated in those studies? A. Over 700. 552 Q. And, the slide says that the study has been presented at medical conferences or published. Describe for the jury what that means. A. So, that means when the studies are complete that all of these studies have either been presented at those medical society conferences. So, again, that means the physician is standing there presenting the data or has published the data in a poster format and can speak to it that way. Or the data were presented -- published in a medical journal in the form of a manuscript.	Plaintiffs cannot discern which studies are being presented through the exhibit.	
jc042115, (Pages 564:23 to 567:18) 564 (Exhibit 1344 marked for identification) Q. (By Mr. Anielak) Now I want to talk 565 about Uphold. And, I've marked as deposition Exhibit 1344 a summary of the clinical trials of Uphold? A. Yes. Q. And, how many clinical studies have been done with Uphold? A. 16. Q. Okay. And, in terms of the number of women. How many women have received Uphold as part of those studies? A. It's been over 800. Q. And, how long have patients been followed in this particular study? A. In these studies it ranges from one month to over two and a half years. Q. And, we talked about the investigators in the studies.	564:23-567:18 FRE 401; 402; 403; 1006 Plaintiffs cannot discern which studies are being presented through the exhibit.	

Again, describe for the jury what an investigator does. A. An investigator is the physician who treats the patients, follows the patients, and collects the data. So, it's a research physician. 566 Q. And, in looking at all of the Uphold studies, what do the Uphold studies show in terms of the effectiveness of Uphold in treating patients? A. It shows that it's effective. It works. So, from -- and why I can say that is the effectiveness is assessed by objective measurements. So, again, the anatomy, where is that pelvic organ prolapse at. Is it better than it was before surgery. So, that's from the objective standpoint. And the studies also show from the patients standpoint their reports of symptoms that were due to their pelvic organ prolapse are improved significantly. So, before surgery to after surgery, those symptoms are significantly improved. Q. And, do the studies also look at the safety of the Uphold device? A. Yes. Q. And, how do they go about doing that? A. So, I ask the physician questions that during the physical exam does he see, feel anything, see if there is anything going on with 567 the patient. Also the patients are reporting events to the physician. So, if the patient reports pain, exposure, if they're aware of it, they report that to the physician, the physician reports it in the studies, and it gets published in these papers. So, we can tell by looking at all these papers that the reports that are coming in on the product in the studies is within a range for what we know is to be expected. There aren't any trends or significant variations in reports or any adverse events that have not been reported before. And they're similar to other products that are on the market. Q. And, in terms of the clinical studies that have been done on Uphold, do they	566:1-567:18 FRE 401; 403; 701; 702; 801; 802 Interpretation of unidentified studies.	

17 support the safety of the device? 18 A. They do.		
jc042115, (Pages 569:23 to 572:13) *** 25 Q. And, do you agree that that's a 572 1 reasonable conclusion based on their data? 2 A. I do, based on their data and how 3 they reported their information and how they -- 4 and the safety and effectiveness results. ***	571:25-572:4 FRE 401; 402; 403 701;702	
jc042115, (Pages 572:17 to 573:13) *** 21 Q. And, do you believe that that's a 22 reasonable conclusion based on their data? 23 A. I do, yes. 24 Q. And, in terms of the overall studies 25 that have been conducted on Uphold, including the 573 1 Jirschele study, do all of the uphold studies 2 support the safety and effectiveness of the 3 device? 4 A. They do, yes. 5 Q. And, are those studies also looking 6 at similar ways in terms of evaluating 7 effectiveness? 8 A. Yes. So, all the studies report on 9 safety. And they all report on the success of 10 the procedure, which is the effectiveness and 11 where the anatomy landmarks are. So that's that 12 grading system, but also where the patients 13 reports were.	572:21-573:13 FRE 401; 403; 701;702; 801; 802 Interpretation of unidentified studies.	
jc042115, (Page 577:18 to 577:21) 577 18 What is the expectation of Boston 19 Scientific regarding whether doctors should have 20 an appreciation for the information that's 21 available on the devices?	577:18-578:21 401, 402, 403, Foundation	
jc042115, (Pages 577:24 to 578:17) 577 24 THE WITNESS: In out -- we do have 25 an expectation. 578 1 So, in our directions for use we 2 actually do indicate that physicians should	577:18-578:21 401, 402, 403, Foundation	

read the literature. So, obviously, the literature gets updated as often as studies are completed. These medical journals are monthly subscriptions. So, each month there is new studies that are coming out. So, we do expect physicians to review the literature. They're implanting the products and they're using the products so they should have an understanding. Q. (By Mr. Anielak) And, is it your experience that doctors do, in fact, have an understanding about what the literature says based on your interaction with doctors at conferences and other places?		
jc042115, (Pages 578:19 to 579:2) 578 THE WITNESS: Yes, it is. And, the reason why I answer that yes is when I talk to the physicians about current research or ideas on doing research, they know the studies in their heads. So, they're actually able to, without anything in front of them, talk about certain studies that 579 are published, and what the results showed in certain study designs.	578:18-579:2 FRE 401, 402, 403, Foundation, Speculative	

Objections to BSC Exhibtis

1. 1328 – Plaintiffs object under FRE 401 and 403 to the portion of the exhibit tabbed "stress incontinence." These products are not at issue in this case and planned trials on these devices will mislead the jury.

2. 1329 – Plaintiffs object under FRE 401 and 403 to the exhibit in its entirety. Post implantation clinical trials have no relevance BSC's conduct in 2010. Additionally, the exhibit reference non POP products and contains impermissible references to FDA.

3. 1332 – Plainitff object under FRE 401 and 403 to the exhibit in it's entirely as it focuses on slings. Additionally, Plaintiffs object under FRE 1006 as BSC has not produced or identified the underlying source materials being presented through the exhibit.

4. 1339 – Plaintiffs object as the exhibit lacks proper foundation. Plaintiffs cannot discern which studies were included/excluded. Additionally, Plaintiffs object under FRE 1006 as BSC has not produced or identified the underlying source materials being presented through the exhibit.

5. 1344 - Plaintiffs object as the exhibit lacks proper foundation. Plaintiffs cannot discern which studies were included/excluded. Additionally, Plaintiffs object under FRE 1006 as BSC has not produced or identified the underlying source materials being presented through the exhibit.

Counter Exhibits

1. Connor 1323

DATED: June 26, 2015

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 26, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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